



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,393	11/21/2006	Naoko Horikoshi	1004451.001US (4439-4045)	3674
27123 7590 11/12/2010 MORGAN & FINNEGAN Transition Team C/O Locke Lord Bissell & Liddell 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 11/12/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Shopkins@Lockelord.com
OWalker@Lockelord.com

Office Action Summary	Application No. 10/584,393	Applicant(s) HORIKOSHI ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 5-8,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9,11-15 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/18/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claim(s) 1, 2, 4-9, and 11-18 are pending. Claim(s) 1, 2, 4, 9, 11-15, and 18 are under examination. The following Office Action is in response to Applicant's communication dated October 28, 2010.

Information Disclosure Statement

Upon further review, it was discovered that references WO 95/05461 and EPO 0552571 A1 were incorrectly crossed out on the IDS filed May 18, 2010. As such a corrected IDS is attached to this Office Action.

Claim Rejections - 35 USC § 112 - Indefiniteness - Withdrawn

Applicant's claim amendments are sufficient to overcome the rejection of claim(s) 1, 2, 4, 9, 11-15, and 17 presented in the Office Action dated July 28, 2010. Thus, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103 - Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim(s) 1, 2, 9, 11, 12, and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hsih et al. (J Food Prot. 2001 Nov;64(11):1744-50) in view of Kearney et al. (U.S. 5,589,335), and in further view of Brasher et al. (Curr Microbiol. 1998 Aug;37(2):101-7).

Hsih teaches methods of detecting *Salmonella typhimurium* and *Listeria monocytogenes* comprising: (a) extracting DNA; and (b) performing multiplex PCR (pg. 1745, col. 2, multiplex PCR conditions, for example). The reference expressly teaches that UP broth was used such that both bacteria could grow simultaneously (pg. 1745, col. 1, culture conditions). The UP broth appears analogous to the medium No. 17 used by Applicant on pg. 23 of specification (0.5 g glucose).

Hish does not expressly teach treating bacterial samples with a lytic enzyme, a surfactant, and a protein denaturant.

Kearney provides a supportive disclosure that teaches lysing a bacterial sample comprising *E. coli* and *L. monocytogenes* with lysozyme, bacteriocin, and proteinase K (col. 17, lines 50-65, for example).

None of the above references expressly teach the use of a surfactant during cellular lysis.

Brasher provides a supportive disclosure that teaches lysing a bacterial sample comprising *E. coli* and *S. typhimurium* with SDS and proteinase K followed by centrifugation and DNA precipitation with alcohol (pg. 102, col. 1, genomic DNA extraction, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to utilize a combination of a lysozyme, bacteriocin, surfactant, and protein denaturant to lyse the bacterial samples of Hsih since the prior art exemplifies each reagent as useful for lysing the different types of bacteria in Hsih.

Applicant is reminded that the "teaching, suggestion, or motivation" (TSM) test should not be applied as a rigid formula for determination of obviousness. In a recent case before the Supreme Court, *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the court addressed the TSM test, reciting the following,

"The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In

Art Unit: 1637

many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility."

Furthermore, in *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006), the court found that,

"Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense,...,Indeed, we have repeatedly held that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the "improvement" is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references,...,Persons of varying degrees of skill not only possess varying bases of knowledge, they also possess varying levels of imagination and ingenuity in the relevant field, particularly with respect to problem-solving abilities."

Thus, the courts have concluded that any reasoned argument grounded in the analysis set forth in *Graham et al. v. John Deere Company of Kansas City et al.*, 148 USPQ 459 (U.S. 1966), may form the basis for a *prima facie* case of obviousness.

In the instant case, a person of ordinary skill in the art would have possessed the knowledge necessary to create the claimed lysis combination to lyse the different bacteria of Hsih in a reasonably predictable manner.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

First, in response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With specific regard to Applicant's arguments regarding Hsih (see remarks pg. 8-9), Applicant is respectfully reminded that the claimed invention is recited in "comprising" or open language which allows for the inclusion outside steps such as immunomagnetic separation. Based on the combination of references, a person of ordinary skill in the art at the time of invention would have possessed the knowledge to utilize a combination of a lysozyme, bacteriocin, surfactant, and protein denaturant to lyse the bacterial samples within the methods of Hsih since the prior art exemplifies each reagent as useful for lysing the different types of bacteria in Hsih.

Furthermore, MPEP 2142 exemplifies certain rationales for establishing obviousness such as: 1) use of known technique to improve similar devices (methods, or products) in the same way; 2) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results. In the instant case, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to add known lysis agents for known bacteria to the methods of Hsih to provide for the increased likelihood of obtaining an appropriate amount of DNA for subsequent amplification.

With specific regard to Applicant's arguments regarding Kearny and Brasher (see remarks pg. 8-9), both references exemplify combination of lysis reagents suitable for extraction cellular DNA. A person of ordinary skill in the art at the time of invention would have possessed the knowledge to provide for the appropriate combination of lysis reagents for a combination of *L. monocytogenes* (gram-positive bacteria) and gram-negative bacteria within the methods of Hsih. The examiner is not proposing a simple combination of all teachings from each reference without any regard for the potential pitfalls of such combinations.

Applicant is further directed to MPEP 2141 which expressly recites,

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR, 550 U.S. 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."Id. Office personnel may also take into account 'the inferences and creative steps that a person of ordinary skill in the art would employ.'Id. 82 USPQ2d at 1396. In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are 'persons of scientific competence in the fields in which they work' and that their findings are 'informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art.' *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

In the instant case, a person of ordinary skill in the art at the time of invention would have recognized the appropriate enzyme combinations for the specific cellular types, thereby coming to the combination recited in the claimed invention.

Thus, the rejection is maintained.

2. Claim(s) 4 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hsih et al. (J Food Prot. 2001 Nov;64(11):1744-50) in view of

Art Unit: 1637

Kearney et al. (U.S. 5,589,335), in view of Brasher et al. (Curr Microbiol. 1998 Aug;37(2):101-7) as applied to claim 1 above, and in further view of Rimick et al. (U.S. 6,468,743 B1) , in view of Buck et al ("Design Strategies and Performance of Custom DNA Sequencing Primers" Biotechniques. 1999. 27(3): pages 528-536), and in further view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 1757-1761, 1990).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach the primer sequences recited in SEQ ID NOs: 5 and 6.

However, it is first noted that the *L. monocytogenes* target sequence for example, the sequence from which the claimed oligonucleotides were derived, is a sequence that was well known at the time of invention (see Rimick SEQ ID NO: 59). Thus, the binding site of SEQ ID NOs: 5 for example is suggested within the sequence disclosed by Rimick (see alignment of Rimick SEQ ID NO: 59 with SEQ ID NO: 5 for example below).

Art Unit: 1637

```

RESULT 2
AR238655
LOCUS       AR238655                40 bp    DNA        linear    PAT 20-DEC-2002
DEFINITION  Sequence 59 from patent US 6468743.
ACCESSION   AR238655
VERSION     AR238655.1  GI:27283725
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 40)
  AUTHORS   Romick,T.L. and Fraser,M.S.
  TITLE     PCR techniques for detecting microbial contaminants in foodstuffs
  JOURNAL   Patent: US 6468743-A 59 22-OCT-2002;
            ConAgra Grocery Products Company; Fullerton, CA
FEATURES             Location/Qualifiers
     source          1..40
                     /organism="unknown"
                     /mol_type="genomic DNA"
ORIGIN

Query Match      100.0%;  Score 20;  DB 2;  Length 40;
Best Local Similarity  100.0%;  Pred. No. 10;
Matches   20;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy      1  CGGAGGTTCCGCAAAAGATG 20
        |||||
Db      1  CGGAGGTTCCGCAAAAGATG 20

```

Applicant is directed to *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Since the claimed sequences simply represent structural homologs of those sequences disclosed in the prior art, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed

Art Unit: 1637

primers (SEQ ID NOs: 5 and 6) is *prima facie* obvious over the cited references in the absence of secondary considerations.

Buck provides a supporting disclosure that expressly presents evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

In addition to teachings of Buck, Lowe provides a supportive disclosure that teaches a method for designing primers and evaluating their performance wherein a computer program is used for rapid selection of oligonucleotide primers for polymerase

Art Unit: 1637

chain reaction (see page 1757, col. 1, abstract). The reference teaches that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probe (see page 1760, col. 2, paragraph 1).

As explained above, the claimed sequences simply represent structural homologs of those sequences disclosed in the prior art, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers (SEQ ID NOs: 5 and 6) are *prima facie* obvious over the cited references in the absence of secondary considerations.

Furthermore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention, to combine the known *L. monocytogenes* nucleic acid sequences as taught by the prior art with a step of generating and designing primers as taught by Hsih to detect the presence of *L. monocytogenes* because such genomic sequences were known (Rimick) at the time the invention was made, and it is obvious to generate primers from known sequences as taught by Lowe. The ordinary artisan would have had a reasonable expectation of success that such primers or primer pairs generated using known sequences as taught by Rimick in view of Lowe to amplify *L. monocytogenes* sequences for detection because the claimed primers are functional equivalents of the sequences taught by Hsih, Rimick, and Lowe explicitly taught that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted

Art Unit: 1637

size (see page 1760, col. 2, paragraph 1). The ordinary artisan would have been motivated to generate a number of said primers and primer pairs for detection of *L. monocytogenes* sequences to provide flexibility and optimize experimentation.

Selection of specific oligonucleotides for specific T_m represents routine optimization with regard to sequence, length and composition of the oligonucleotide. Such optimization parameters are explicitly recognized in Lowe (This clearly shows that every primer would have a reasonable expectation of success). As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

It is noted that a sufficient showing of a secondary consideration (e.g. unexpected results) would obviate this and any further rejection of this type. Submission of a secondary consideration such as latent properties must be supported by objective evidence of a probative value (see MPEP 716.01).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

As recited above, structural relationships may provide the requisite motivation or

Art Unit: 1637

suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see *In Re Deuel* above).

Thus, absent a secondary consideration, the rejection is maintained.

3. Claim(s) 14 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (J Food Prot. 2001 Nov;64(11):1744-50) in view of Kearney et al. (U.S. 5,589,335), in view of Brasher et al. (Curr Microbiol. 1998 Aug;37(2):101-7) as applied to claim 1 above, and in further view of Bussey et al. (U.S. 6,011,148).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach the use of Tween 20.

Bussey provides a supportive disclosure that teaches,

"...plasmid DNA may be isolated from bacterial sources using conventional procedures including lysis with alkali and/or detergents, e.g. SDS, NP40, Tween 20 and the like, mechanical methods, or boiling, followed by precipitation of proteins, chromosomal DNA and cell debris. (see Sambrook, et al., 1989; Carlson et al., 1995, Biotech. Bioeng. 48: 303-315; Hirt, 1967, J. Mol. Biol. 26: 365-369)." (col. 5)

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to utilize Tween 20 in the lysis

Art Unit: 1637

mixture of Hsieh since the prior art highlights Tween 20 as a functional equivalent of SDS.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The examiner recognizes the differences between the teachings. As recited above, the examiner is not proposing a simple combination of all teachings from each reference without any regard for the potential pitfalls of such combinations. The fact is the prior art recognizes Tween 20 as an appropriate lysis reagent. A person of ordinary skill in the art at the time of invention would have possessed the knowledge to provide for the appropriate combination of lysis reagents

Thus, the rejection is maintained.

4. Claim(s) 15 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (J Food Prot. 2001 Nov;64(11):1744-50) in view of Kearney et al. (U.S. 5,589,335), in view of Brasher et al. (Curr Microbiol. 1998 Aug;37(2):101-7) as applied to claim 1 above, and in further view of Anzar et al. (Syst Appl Microbiol. 2002 Apr;25(1):109-19).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach the use of guanidinium isothiocyanate.

Art Unit: 1637

Anzar provides a supportive disclosure that teaches lysing a bacterial sample comprising *L. monocytogenes* with guanidium isothiocyanate (pg. 110, col. 2, DNA isolation, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to utilize guanidium isothiocyanate in the lysis mixture of Hsih since the prior art highlights guanidium isothiocyanate as a functional equivalent of proteinase K.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

As recited above, the examiner is not proposing a simple combination of all teachings from each reference without any regard for the potential pitfalls of such combinations. The fact is the prior art recognizes both guanidium isothiocyanate and Proteinase K as cellular lysis reagents. A person of ordinary skill in the art at the time of invention would have possessed the knowledge to provide for the appropriate combination of lysis reagents

Thus, the rejection is maintained.

Claim Rejections - 35 USC § 103 - New Grounds

Claim(s) 13 is under 35 U.S.C. 103(a) as being unpatentable over Hsih et al. (J Food Prot. 2001 Nov;64(11):1744-50) in view of Kearney et al. (U.S. 5,589,335),

Art Unit: 1637

in view of Brasher et al. (Curr Microbiol. 1998 Aug;37(2):101-7) as applied to claim 1 above, and in further view of Nilsen et al. (Appl Environ Microbiol. 2003 May;69(5):2975-84).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach the use of enterolysin.

Nilsen provides a supportive disclosure that teaches Enterolysin A as a cell wall-degrading bacteriocin (abstract, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to utilize Enterolysin A in the lysis mixture of Hsih since the prior art highlights such protein as lysis agent.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner
Art Unit 1637
Technology Center 1600